K 000115

MAR 27 2000

510(k) Summary of Safety and Effectiveness

510(k) Submitter:	Streck Laboratories, Inc. P.O. Box 45625 Omaha, NE 68145-0625
Official Correspondent:	Paul Kittelson Quality Assurance/Regulatory Affairs (402) 691-7465
Date Prepared:	January 11, 2000
Names of Device:	
Trade Name:	Retic Chex Linearity
Common Name:	Hematology linearity material
Classification Name:	Hematology quality control mixture (§ 864.8625)
Predicate Device:	Retic Chex (K905524) manufactured by Streck Laboratories

Description: Retic Chex Linearity is a suspension of stabilized human red blood cells and simulated human reticulocytes packaged in glass vials containing 1.0 mL volumes. Closures are injection molded polypropylene screw-top caps. The vials are packaged in polystyrene jars.

Intended Use: Retic Chex Linearity is a calibration (linearity) assessment kit designed for use on the following automated reticulocyte analyzers: Bayer Advia 120, Sysmex R-3000, Sysmex XE-2100, and Abbott Cell-Dyn 4000. It is intended to allow users to satisfy CAP requirements and CLIA recommendations to verify patient reportable ranges.

Comparison with Predicate Device: Like Retic Chex, Retic Chex Linearity is a multi-level device intended for validation of reticulocyte analysis on a variety of automated hematology instruments. Both devices contain stabilized human red blood cells and simulated human reticulocytes which properly mimic human whole blood on the intended-use analyzers.

Unlike Retic Chex, the four levels of Retic Chex Linearity cover a range of reticulocyte percentages which more closely resemble the patient reportable ranges for each of the intended-use analyzers. Additionally, Retic Chex Linearity comprises a true linearity, and can be used to validate linear operation of the analyzers listed above.

Discussion of Tests and Test Results: Four studies of Retic Chex Linearity were conducted: I) Run to Run Reproducibility and Comparison to Whole Blood; II) Site to Site Reproducibility; III) Long Term Stability; and IV) Open Vial Stability. Study results showed Retic Chex Linearity to be consistently reproducible, substantially equivalent to the predicate product, and stable for the entire product dating.

Conclusions Drawn From Tests: Retic Chex Linearity is a safe and effective reticulocyte calibration (linearity) assessment kit for the intended hematology instruments listed above when used as instructed in the product package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 27 2000

Mr. Paul Kittelson
Quality Assurance/Regulatory Affairs
Streck Laboratories, Inc.
14124 Industrial Road
Omaha, Nebraska 68144

Re: K000115
Trade Name: Retic Chex Linearity
Regulatory Class: II
Product Code: JPK
Dated: March 6, 2000
Received: March 14, 2000

Dear Mr. Kittelson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K000115

Device Name: RETIC-CHEX® Linearity

Indications For Use:

Retic-Chex Linearity is a multi level calibration (linearity) assessment kit for reticulocyte counting. It is designed for use on the following instruments: Bayer Advia 120, Sysmex R-3000, Sysmex XE-2100, and Abbott Cell-Dyn 4000. Use of this kit allows users to satisfy CAP requirements and CLIA recommendations to verify patient reportable ranges.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000115

Prescription Use ✓ OR **Over-The-Counter Use**_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)